



[BILLING CODE 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; 30-day comment request: Application for Collaboration with the Therapeutic Development Branch (TDB), Division of Preclinical Innovation (DPI), National Center for Advancing Translational Sciences (NCATS)

SUMMARY: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Center for Advancing Translational Sciences (NCATS), the National Institutes of Health, has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below. This proposed information collection was previously published in the Federal Register on November 21, 2014, page 69499 and allowed 60-days for public comment. No public comments were received. The purpose of this notice is to allow an additional 30 days for public comment. The National Center for Advancing Translational Sciences (NCATS), National Institutes of Health, may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

DIRECT COMMENTS TO OMB: Written comments and/or suggestions regarding the

item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, OIRA_submission@omb.eop.gov or by fax to 202-395-6974, Attention: NIH Desk Officer.

COMMENT DUE DATE: Comments regarding this information collection are best assured of having their full effect if received within 30 days of the date of this publication.

FOR FURTHER INFORMATION: To obtain a copy of the data collection plans and instruments, or request more information on the proposed project, contact: Dr. Nora Yang, Therapeutic Development Branch, DPI, NCATS, NIH, 9800 Medical Center Drive, Building B, Rockville, MD 20850, or call non-toll-free number (301)-217-1077 or E-mail your request, including your address to: TRND@mail.nih.gov. Formal requests for additional plans and instruments must be requested in writing.

PROPOSED COLLECTION: Application for Collaboration with the Therapeutic Development Branch (TDB), Division of Preclinical Innovation (DPI), National Center for Advancing Translational Sciences (NCATS), 0925-0658, Expiration Date 06/30/2015 - EXTENSION, National Center for Advancing Translational Sciences (NCATS), National Institutes of Health (NIH).

Need and Use of Information Collection: The Therapeutic Development Branch (TDB) provides opportunities to partner with and gain access to a variety of programs

delivering assay development, screening, hit-to-lead chemistry, lead optimization, chemical biology studies, drug development capabilities, expertise, and clinical/regulatory resources in a collaborative environment, with the goal of moving promising therapeutics into human clinical trials for both common and specifically rare and/or neglected diseases. The TDB uses an application and evaluation process to select collaborators. Selected investigators provide the drug project starting points and ongoing biological/disease expertise throughout the project. The application and evaluation process is necessary to determine amount and quality of current data, select meritorious projects for adoption, and serve as a basis for determining specific scientific gaps to be filled. OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 510.

Estimated Annualized Burden Hours

Form Name	Number of Respondents	Number of Responses per Respondent	Average Time Per Response (in hours)	Total Annual Burden Hours
TDB Project Information Template	170	1	1	170
Online Collaborator Solicitation (TRND)	100	1	1	100
Online Collaborator Solicitation (BrIDGs)	70	1	1	70
Solicitation Instructions (TRND)	100	1	1	100
Solicitation Instructions (BrIDGs)	70	1	1	70

Dated: March 4, 2015

M. Janis Mullaney, MBA

Associate Director for Administration

NCATS, NIH

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